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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--------------------------|---------------------|------------------|
| 10/613,434 | 07/03/2003 | Aleksandar Milosavljevic | GMX 071394 | 4478 |
| 7590 | 10/05/2006 | | EXAMINER | |
| Robert D. Touslee GMX Technology Inc. 29 Golden Eagle Lane Littleton, CO 80127 | | | DEJONG, ERIC S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------------|----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/613,434 | MILOSAVLJEVIC ET AL. |
| | Examiner Eric S. DeJong | Art Unit 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 61-80 is/are pending in the application.
- 4a) Of the above claim(s) 74 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 61-73 and 75-80 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07/03/2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>06/06/2005</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Election/Restrictions

Applicant's election of Species A (claims 73 and 75), drawn to a sample comprising a polynucleotide, in the reply filed on 07 July 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 74 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07 July 2006.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the

requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 09/632,539 and 60/161,694, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Claim 61 recites the limitation "samples stored in substantially desiccated form" in lines 4 and 5 of said claim. Claim 72 recites the limitation of "providing a repository capable of storing a plurality of samples derived from biological sources in substantially desiccated form" in lines 2 and 3 of said claim. Claim 78 recites the limitation of "identifying a sample stored in substantially desiccated form stored in a repository" in lines 7 and 8 of said claim. Upon review of the prior-filed applications, Application No. 09/632,539 and 60/161,694, no support has been found for biological sources in substantially desiccated form or a disclosure of a repository that is capable storing biological sources in substantially desiccated form. Accordingly, claims 61-73 and 75-80 are not entitled to the benefit of the prior applications.

Drawings

The drawings were received on 03 July 2003. These drawings are not acceptable because the replacement drawing for Figure 5 now contains the additional reference character "5(a)", which does not appear in the Brief Description of the Drawings for figure 5 in the instant specification. 37 CFR § 1.84(p)(5) states that reference characters not mentioned in the description shall not appear in the drawings.

Applicants must either submit drawings that are in full compliance with 37 CFR § 1.84, or, alternatively, amend the instant specification for the description of figure 5 so as to reflect the additional reference character “5(a)” present in the replacement drawing for Figure 5.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 61 recites the limitation “samples stored in substantially desiccated form” in lines 4 and 5 of said claim. Claim 72 recites the limitation of “providing a repository capable of storing a plurality of samples derived from biological sources in substantially desiccated form” in lines 2 and 3 of said claim. Claim 78 recites the limitation of “identifying a sample stored in substantially desiccated form stored in a repository” in lines 7 and 8 of said claim. As noted above, Application Nos. 09/632,539 and 60/161,694 do not provide support for either biological sources in substantially desiccated form or a repository that is capable storing biological sources in substantially desiccated form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 61-73 and 75-80 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Hodge et al. (US Patent No. 6,977,178).

The instant claims are drawn to methods of providing selective biological samples from a sample archive comprising providing a sample repository of a plurality of samples derived from biological sources, wherein said samples are stored in substantially desiccated form, providing an information database comprising medical history, clinical, or phenotypic information associated with said biological sources, determining a request from a sample selected from said plurality of samples, and removing at least a portion of said sample based upon said request.

Hodge et al. sets forth methods and related apparatuses for conducting transgenic and targeted mutagenesis screening of genomic DNA (see Hodge et al., Abstract). Hodge et al. discloses that the methods and systems includes a computer having a processor, memory and web browser, wherein the computer receives instructions concerning the designated genetic sequence and other screening parameter selection from a remote user via a form of electronic communication, and an

automatic screening device that analyzes samples of genomic DNA for the designated sequence (see Hodge et al., Abstract and Figures 1 and 2).

Hodge further discloses that one object of the disclosed methodology involves depositing prokaryotic or eukaryotic genomic DNA on a substrate and detecting the genomic DNA with a microarray imager to facilitate high volume screening (see Hodge et al., col. 2, line 57 through col. 3, line 15). Additionally, the disclosed methodology comprises an order process that provides a remote user's selection parameters to conduct screening of a sample and provides the associated reagents, in a coordinated way facilitates high volume screening of transgenic and targeted mutagenesis samples for a designated genetic sequence. In addition, Hodge et al. further sets forth that the disclosed methodology is directed to the screening of genomic DNA from cellular lysate using magnetic particles and lysing the tissue sample with a lysis buffer that is formulated to work while the samples are in transit to the screening laboratory from a remote user.

Hodge et al. sets forth the use of an array station and an optical standardization technique wherein genomic DNA is deposited on the surface of a wells on a substrate (see Hodge et al. col. 20, line 48 through col. 21, line 47). The disclosed array station includes software that tracks the location of specific sample its particular position in an array. Hodge further set forth that the optical standardization station performs adjustments based on known sample volumes in secondary master well plates with the known DNA concentration to calculate the volume to hydrate or the time to desiccate each sample (see col. 21, lines 1-15).

Hodge et al. further discloses exemplary embodiments wherein information regarding clinical and phenotypic information regarding requested samples is ascertained, recorded and included with test results (see Examples 1-4 of Hodge et al., col. 29, line 65 through col. 35, line 58). Example 1 demonstrates that a information regarding the nature of a control, specifically zygosity and copy number, is provided (see Hodge et al., col. 30, lines 38-50). Example 4 further demonstrates the use of sample amplification using PCR (see col. 33, line 36 through col. 34, line 37). Hodge et al. further sets forth that screening methods may be used wherein at least one labeled target binding probe and at least one labeled reference binding probe is provided (see Hodge et al., col. 4, lines 35-60).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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